



8-16-04

PHA 42641.1  
PATENT

IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Diane T. Stephenson et al.

Art Unit 1617

Serial No. 10/828,734

Filed April 21, 2004

Confirmation No. 4758

For COMPOSITIONS OF A CYCLOOXYGENASE-2 SELECTIVE INHIBITOR AND A  
POTASSIUM ION CHANNEL MODULATOR FOR THE TREATMENT OF PAIN,  
INFLAMMATION OR INFLAMMATION MEDIATED DISORDERS

August 13, 2004

COMMISSIONER FOR PATENTS

P.O. BOX 1450

ALEXANDRIA, VIRGINIA 22313-1450

SIR:

**INFORMATION DISCLOSURE STATEMENT**

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicant submits the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the OG notice of August 5, 2003 partially waiving the requirements of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S. patent documents are not supplied. Applicant submits herewith copies of the foreign patent documents and literature references.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) in that applicants believe that it is being filed prior to the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. §1.97(c) or (d) is required. However, if an Office action was issued prior to the date of mailing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge any required fees regarding this Information Disclosure Statement to Deposit Account No. 19-1345.

Respectfully submitted,

Edward J. Hejlek, Reg. No. 31,525  
SENNIGER POWERS  
One Metropolitan Square, 16th Floor  
St. Louis, Missouri 63102  
(314) 231-5400

EJH/cms

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PTO/SB/08A				<b>Complete if Known</b>	
<b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				Application Number	10/828,734
				Filing Date	April 21, 2004
				Confirmation Number	4758
				First Named Inventor	Diane T. Stephenson
				Group Art Unit	1617
				Examiner Name	
Sheet	1	of	2	Attorney Docket No.	PHA42641.1 (01382/2/US)

### U.S. PATENT DOCUMENTS

Examiner Initials*	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	1	5,466,823		Talley et al	11/14/1995
	2	5,521,207		Granelo	05/28/1996
	3	5,633,272		Talley et al	05/27/1997
	4	5,932,598		Talley et al	08/03/1999
	5	6,034,256		Carter et al	03/07/2000
	6	6,077,850		Carter et al	06/20/2000

### FOREIGN PATENT DOCUMENTS

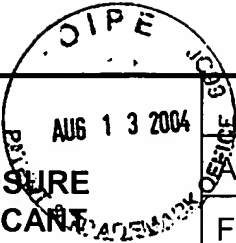
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T <sup>6</sup>
		Office	Number <sup>4</sup>	Kind Code <sup>2</sup> (if known)			
	7	WO	91/08760		Brigham and Women's Hospital	06/27/1991	
	8	WO	92/16192		Amgen Inc.	10/01/1992	
	9	WO	98/03484		Merck Frosst Canada Inc.	01/29/1998	
	10	WO	00/24719		Abbott Laboratories	05/04/2000	

Examiner Signature		Date Considered	
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup>Unique citation designation number. <sup>2</sup>See attached Kinds of U.S. Patent Documents. <sup>3</sup>Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup>For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup>Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup>Applicant is to place a check mark here if English language Translation is attached or place an "A" here if English language abstract is attached..

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PTO/SB/08A				<b>Complete if Known</b>	
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Sheet	2	of	2	Attorney Docket No.	PHA42641.1 (01382/2/US)

OTHER ART - NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	11	ASANO et al, Masui, 1996, 45(11): 1342-1346 (English abstract and Japanese article)	
	12	BEEKWILDER et al, "Kv1.1 Channels of Dorsal Root Ganglion Neurons are Inhibited by <i>n</i> -Butyl- <i>p</i> -aminobenzoate, a Promising Anesthetic for the Treatment of Chronic Pain", Journal of Pharmacology and Experimental Therapeutics ,2002, 304(2): 531-538	
	13	BLEDNOV et al, "A Pervasive Mechanism for Analgesia: Activation of GIRK2 Channels", PNAS, 2003, 100(1): 277-282	
	14	GIERSE et al, "Expression and Selective Inhibition of the Constitutive and Inducible Forms of Human Cyclo-oxygenase", Biochemical Journal, 1995, 305: 479-484	
	15	HARGREAVES et al, "A New and Sensitive Method for Measuring Thermal Nociception in Cutaneous Hyperalgesia" Pain, 1988, 32: 77-88	
	16	NEWMAN, "Aerosols and the Lung: Clinical and Experimental Aspects", Chapter 9 - "Therapeutic Aerosols", Butterworths, London, England, 1984, p. 197-224	
	17	SIEGMUND et al, "A Method for Evaluating both Non-Narcotic and Narcotic Analgesics", Proceedings of the Society for Experimental Biology and Medicine, 1957, 95: 729-31	
	18	WINTER et al, "Carrageenin-Induced Edema in Hind Paw of the Rat as an Assay for Antiinflammatory Drugs", Proceedings of the Society for Experimental Biology and Medicine, 1962, 111(3): 544-547	

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